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EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/523,455	ENGEL ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2005 has been entered.

Applicants arguments regarding the rejection of claims 1 and 4-24 under 35 U.S.C. 103(a) as being obvious over Engel, Albano, Felberbaum and Garfield in view of Deghenghi, Rabasseda and Kent (all of record) have been fully considered and have been found persuasive in light of Applicant's amendments to the claim. In particular, the references do not provide sufficient motivation to combine administration of an LhRH antagonist, a progestogen only preparation or a combined oral contraceptive starting during the luteal phase, as recited in part (a) of claim 1, with the steps of stimulation of the ovarian follicle growth, suppression of premature ovulation, induced ovulation and application of assisted reproduction techniques, as recited in steps (b)-(e). Accordingly, the prior rejection is withdrawn.

The claims are being newly rejected as follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-24 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the specification does not provide support for "resetting the menstrual cycle" as recited in claim 1, and instead only provides support for the "programming of ovarian stimulation procedures," as for example taught in the first full paragraph on page 3 of the specification. Appropriate correction and/or clarification is required.

Claims 1 and 4-24 are furthermore rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, because the specification as filed does not provide support for "the progestogen and/or the combined oral contraceptive preparations are administered starting during both the luteal phase and day 1 or 2 of the menstrual cycle" (emphasis added) as recited in claim 1. Instead, the specification discloses that "oral contraceptives or progestogen-only containing preparations are given in the follicular phase, preferably starting at menstrual cycle day

1 or 2, or in the late luteal phase of the previous menstrual cycle" (emphasis added), as taught on page 3 of the specification. Thus, the specification provides support for starting either during the late luteal phase or day 1 or 2 of the menstrual cycle, but does not provide support for starting on both. Appropriate correction and/or clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-24 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for reciting that "the progestogen and/or the combined oral contraceptive preparations are administered staring during both the luteal phase and day 1 or 2 of the menstrual cycle" (emphasis added) as in claim 1. The claim is indefinite because it is not clear what is meant by starting administration during both the luteal phase and day 1 or 2 of the menstrual cycle. Is it meant that the administration is started during the luteal phase, stopped to allow for normal menstrual cycle to resume, then re-started during day 1 or day 2 of the menstrual cycle? Or is it meant that the "start" of the administration encompasses the entire time from the luteal cycle until what would be day 1 or day 2 of the menstrual cycle? The specification does not provide any guidance as to how to "start" administration at both of these times. Accordingly, the metes and bounds of the claim cannot be readily ascertained, and thus claim 1 is indefinite under

35 U.S.C. 112, second paragraph. Claims 4-24 are rejected as depending from an indefinite claim. Appropriate correction and/or clarification is required.

In the interests of compact prosecution and for the purposes of applying prior art, claim 1 is being interpreted as meaning that the progestogen and/or the combined oral contraceptive preparations are administered staring during either the luteal phase or day 1 or 2 of the menstrual cycle, as taught on page 3 of the specification.

Claims 1 and 4-24 are furthermore rejected under 35 U.S.C. 112, second paragraph, as being indefinite for recited the phrase "application of assisted reproduction techniques, especially IVF, ICSI, GIFT, ZIFT or by intrauterine insemination via sperm injection" (emphasis added) as in claim 1, because the recitation of the specific assisted reproduction techniques that are "especially" used represents the recitation of both a narrower range and a broader range (assisted reproduction techniques in general) within the same claim. The recitation renders the claim indefinite because it is not clear whether the narrower range, i.e. the specific technique such as IVF, is a requirement of the claim, or whether the claim encompasses all assisted reproductive techniques including those not specifically recited. Thus, as the metes and bound of the claim cannot be reasonably determined, the claim is indefinite under 35 U.S.C. 112, second paragraph. See MPEP 2173.05(c). Claims 4-24 are rejected as being dependent upon an indefinite claim. Appropriate correction and/or clarification is required. In the interests of compact prosecution and for the purposes of applying prior

art, claim 1 is being given its broadest possible interpretation to include all assisted reproductive techniques including those not specifically recited.

Claims 5-9 are furthermore rejected under 35 U.S.C. 112, second paragraph, for reciting "the LHRH-antagonist," because it is not clear which antagonist is being referred to in these claims, i.e. the LHRH-antagonist that can be used in the programming step (a) or the LHRH-antagonist that is used in step (c). Appropriate correction and/or clarification is required. In the interests of compact prosecution and for the purposes of applying prior art, claims 5-9 are being given their broadest possible interpretation to mean that the LHRH antagonist is the one that is used either in step (a) or step (c).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-5, 7, 10-11, 16, 18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. (or record) or Albano et al. (of record) or Engel et al (of record) or the article entitled "The Single or Dual Administration of the Gonadotropin-releasing Hormone Antagonist Cetrorelix in an In

Vitro Fertilization-Embryo Transfer Program" by Olivennes et al, 1994, in view of (ii) the article entitled "Synchronization of Endogenous and Exogenous FSH Stimuli in Controlled Ovarian Hyperstimulation (COH)" by Ziegler et al, 1998, and further in view of (iii) U.S. Patent No. 5,470,847 to Garfield et al (of record) or the article entitled "Variable Tolerance of the Developing Follicle and Corpus Luteum to Gonadotropin-Releasing Hormone Antagonist-Induced Gonadotropin Withdrawal in the Human" by Hall et al.

Felberbaum et al. teaches that GnRH antagonists such as Cetrorelix and Ganirelix can be administered in an IVF program to avoid premature LH-surges (see summary, in particular.) Felberbaum et al. teaches that patients are treated with HMG starting on day 2 (see summary, in particular), and thus teaches stimulation of ovarian follicle growth as in part (b). Felberbaum et al. teaches that the patients are administered cetrorelix from day 7 until induction of ovulation with HCG, and thus teaches suppression of premature ovulation by administering the LHRH-antagonist during the follicular cycle as in part (c), and induction of ovulation with HCG as in part (d) (see summary, in particular.) Felberbaum et al. also teaches performing IVF, as in part (e) (see summary in particular.) Thus, Felberbaum et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

Albano et al. teaches a method for assisted reproduction in which an ovarian stimulation protocol is used (see abstract, in particular.) Albano teaches that the

ovarian stimulation method involved administration of HMG during day 2 of the menstrual cycle and administration of the gonadotrophin-releasing hormone antagonist cetrorelix (LHRH antagonist) on day 6 of the menstrual cycle (follicular phase) (see abstract, in particular), and thus teaches steps (b) and (c) of the method. Albano et al. further teaches that ovulation is induced with HCG (see abstract, in particular), and thus teaches step (d). Albano et al. teaches the steps can be performed in a method of in-vitro fertilization (see introduction, in particular), and thus teaches step (e). Thus, Albano et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

Engel et al. teaches the treatment of fertility disorders by administering HMG to hyperstimulate the ovaries (see column 1, lines 10-25, in particular), as in step (b) administering an LHRH antagonist such as cetrorelix during the follicular phase, to reduce premature LH surges during stimulated cycles (see column 2, lines 1-15, in particular), as in step (c), and inducing ovulation with HCG (see column 1, lines 55-60, in particular), as in step (d). Engel et al. teaches that the method can be used in an assisted reproduction technique (see column 3, lines 15-40, in particular. Thus, Engel et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

Olivennes et al. teaches providing a GnRH antagonist such as cetrorelix to prevent premature LH surges in an IVF-ET program (see abstract, in particular.)

Olivennes et al. teaches that controlled ovarian hyperstimulation (COH) is carried out with hMG on day 2 of the menstrual cycle, with cetrorelix being administered during the hyperstimulation (follicular phase) (see abstract, in particular.) Olivennes et al. teaches that ovulation is triggered by administration of HCG (see paragraph bridging pages 469-470, in particular.) Thus, Olivennes et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

The references do not specifically teach programming the start of controlled ovarian stimulation by administration of a compound comprising a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation or a combination thereof, wherein the LHRH-antagonist is administered during the luteal phase and the progestogen only preparation or combined oral contraceptive preparation are administered starting during the luteal phase or day 1 or day 2 of the menstrual cycle.

Ziegler et al. teaches the desirability of permitted advanced timing of the onset of controlled ovarian hyperstimulation (COH) (see page 561, right hand column, in particular.) Ziegler et al. teaches that it is difficult to properly time the onset of HMG administration (see introduction, in particular.) Ziegler et al. teaches that treatments were devised to improve scheduling of treatments for patients and team members by synchronizing FSH rises that initiate new menstrual cycles with the onset of HMG administration for COH (see page 563, left hand column, in particular.) Ziegler et al.

teaches that oestradiol was used for timing the follicular phase increase in FSH to provide for the onset of HMG treatment (see discussion, first full paragraph, in particular), and further teaches that advanced programming of COH has been previously achieved with oral contraceptives (see paragraph bridging pages 563-564, in particular.) Ziegler et al. teaches that the oestradiol treatment was started 7.1 days before the onset of menses (luteal phase) and continued for 5 days thereafter (see results section, in particular.) Thus, Ziegler et al. teaches the desirability of permitting the advanced timing of COH treatments by starting the administration of a composition during the luteal phase to allow for advanced scheduling of treatments.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide advanced timing as taught by Ziegler et al. with the assisted reproductive techniques involving administration of HMG and ovarian stimulation such as COH of Felberbaum et al, Albano et al, Engel et al. and Olivennes et al, because the references teach assisted reproductive techniques involving stimulation with HMG prior to induction of ovulation with HCG, whereas Ziegler et al. teaches that a COH treatment involving HMG ovarian stimulation can be improved by providing advanced timing via administration of a composition to allow for improved scheduling of treatments. Thus, one of ordinary skill in the art would have found it obvious to combine the advanced timing method with the assisted reproductive techniques of Felberbaum et al, Albano et al, Engel et al. and Olivennes et al with the

expectation of improving the efficiency of treatment scheduling and thus fertilization success with the advanced timing method.

Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Ziegler et al. do not specifically teach providing advanced timing by administration of a compound comprising a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation or a combination thereof.

Garfield et al. teaches that progestins and estrogens such as those in the "pill" inhibit the synthesis of LH-RH thus preventing the LH surge which is required for stimulation of growth, maturation and rupture of the Graafian follicle (see column 2, lines 1-20, in particular.) Thus, Garfield et al. teaches that progestins and estrogens such as those used in oral contraceptives can be used to arrest the menstrual cycle and inhibit the development of follicles and ovulation. Garfield teaches that typical contraceptives include combined estrogen and progesterone (a progestogen) as well as progesterone only (see column 2, lines 30-47, in particular.)

The article by Hall et al. teaches that administration of a GnRH antagonist (LHRH antagonist) in the midluteal phase results in luteolysis (see abstract, in particular.) Hall et al. teaches that three daily antagonist injections begun on day 4 or 5 after ovulation (luteal phase) resulted in menstrual bleeding within 24-48 hrs of the final day of the antagonist administration (see page 997, MLP studies, left hand paragraph, in

particular.) Hall t al. teaches that seventy two hours of gonadotropin deprivation (due to GnRH antagonist administration) in the luteal phase resulted in prompt luteolysis in all subjects (see page 998, final paragraph, in particular.) Hall et al. further teaches that in human studies, complete luteolysis is demonstrated in response to GNRH antagonism (see page 999, left hand column first full paragraph, in particular.) Thus, Hall et al. teaches that administration of a GnRH antagonist during the luteal phase results in luteolysis and shortening of the luteal phase. Regarding the specific amount of antagonist administered Hall teaches administering 150 micrograms/kg (see abstract, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of antagonist provided in the method, according to the guidance provided by Hall et al, to provide the desired rate and extent of luteolysis. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Hall et al. does not specifically teach providing an LHRH antagonist that is selected from the group of cetrorelix, teverelix, ganirelix, antide and abavelix. However, as discussed above, Felberbaum et al, Albano et al, Engel et al. and Olivennes et al. teach that cetrorelix is a GnRH antagonists (LHRH antagonist) suitable for administration. Accordingly, it would have been obvious to provide cetrorelix as the

GnRH antagonist in the method of Hall et al. with the expectation of providing a suitable GnRh antagonist.

Accordingly, one of ordinary skill in the art would have found it obvious to provide the progesterone only or combined contraceptive of Garfield et al. or the GnRH antagonist (LHRH antagonist) of Hall et al. in the advanced timing method of assisted reproductive techniques of Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Ziegler et al, because Ziegler et al. teaches the desirability of providing controlled timing to allow for better scheduling of procedures and thus better effectiveness of the procedures, such as by controlling the menstrual cycle via oral contraceptives, whereas Garfield et al. and Hall et al. teach compositions that control the length and duration of the menstrual cycle, to inhibit follicular stimulation and ovulation as in the case of the oral contraceptives of Garfield et al, and to increase the rate of luteolysis and decrease the duration of the luteal phase in the case of Hall et al. Thus, one of ordinary skill in the art would have found it obvious to provide the composition of Garfield et al. or Hall et al, in the method of Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Ziegler et al, with the expectation of providing control of the menstrual phases to provide advanced timing for the assisted reproductive techniques. Thus claim 1 is obvious over the recited references.

, It is respectfully pointed out that the recitation that the method is for "increasing the quality of fertilized oocytes and embryos" to "optimize oocyte harvesting and

fertilization", as recited in claim 1 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.)

Regarding claim 4, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the days on which the compositions are provided, according to the guidance provided by the references, to provide the advanced timing and scheduling of the assisted reproductive techniques. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 5 and 16, the references teach providing cetrorelix as the antagonist during the luteal phase as well as during ovarian stimulation, as discussed above. Regarding claims 7 and 18, Felberbaum et al. teaches administration of ganirelix as a GnRH antagonist, as discussed above. Regarding claims 10-11, Garfield et al. teaches oral contraceptives comprising progestogen and progestogen-only compositions for controlling stimulation of the follicle and ovulation, as discussed above.

Regarding claim 21, the references teach ovarian stimulation with HMG, as discussed above.

Regarding claim 22, Garfield et al. teaches that clomiphene is a non-steroidal antiestrogen that stimulates ovulation by stimulating follicle growth and maturation (see column 3, lines 9-20, in particular.) Accordingly, it would be obvious to incorporate clomiphene into the assisted reproductive techniques as discussed above with the expectation of providing a suitable compound for ovarian stimulation. Regarding claims 23-24, Garfield et al. teaches that clomiphene is an antiestrogen that stimulates follicle growth and ovulation, whereas the Felberbaum et al, Albano et al, Engel et al. and Olivennes et al. references teach that HCG (a gonadotropin) is provided to induce ovulation, as discussed above. Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the clomiphene with the above-described assisted reproductive techniques using the gonadotropin HCG with the expectation of providing suitable stimulation and induction of ovulation for the assisted reproductive techniques.

Claims 6, 8-9, 17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al, and (ii) Ziegler et al, in view of (iii) Garfield et al. or Hall et al, as applied to claims 1, 4-5, 7, 10-11, 16, 18 and 21-24, and further in view of (iv) U.S. Patent No. 5,945,128 to Deghengi et al (of record) or Rabasseda et al (of record.)

Felberbaum et al, Albano et al, Engel et al, Olivennes et al, Ziegler et al, Garfield et al. and Hall et al. are applied as discussed above, and teach providing a GnRH antagonist (LHRH antagonist) such as cetrorelix or ganirelix in the therapeutic fertility management technique as recited in claim 1. The references do not specifically teach providing teverelix, antide or abavelix, as recited in claims 6, 8-9, 17 and 19-20.

Dehgenghi teaches that cetrorelix, teverelix, ganirelix and antide are known to be LHRH antagonists (GnRH antagonists) (see column 2, lines 19-23, in particular.)

Rabasseda et al teaches that LHRH-antagonists (GnRH antagonists) such as cetrorelix, ganirelix and abarelix are known to be useful in the treatment of female infertility (see introduction and Table 1 of page 397, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the antagonists of Deghenghi or Rabasseda et al. in the method of Felberbaum et al, Albano et al, Engel et al, Olivennes et al, Ziegler et al, Garfield et al. and Hall et al, with the expectation of providing a suitable GnRH antagonist (LHRH antagonist) in the method. Furthermore, regarding the specific amount of the antagonist provided, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the antagonist provided in the method, according to the guidance

provided by the references, to provide the desired advanced timing and/or ovulation control. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al, and (ii) Ziegler et al, in view of (iii) Garfield et al. or Hall et al, as applied to claims 1, 4-5, 7, 10-11, 16, 18 and 21-24, and further in view of (iv) U.S. Patent No. 4,016,259 to Kent (of record.)

Felberbaum et al, Albano et al, Engel et al, Olivennes et al, Ziegler et al, Garfield et al. and Hall et al. are applied as discussed above, and teach providing an oral contraceptive combination of a progestogen and estrogen in the therapeutic fertility management technique as recited in claim 1. Garfield et al. further teaches that the oral contraceptive compositions can be administered sequentially (i.e. in phases) (see column 2, lines 20-50, in particular.) The references do not specifically teach providing a combination of progestogen and an estrogen such as ethinyl estradiol or mestranol, as recited in claims 12-15.

Kent discloses that the combination of progestogens and estrogen such as mestranol and ethinylestradiol is useful in animal contraception (see column 1, lines 20-25, in particular.)

Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the contraceptives of Kent into the method of Felberbaum et al, Albano et al, Engel et al, Olivennes et al, Ziegler et al, Garfield et al. and Hall et al, with the expectation of providing a suitable oral contraceptive for the timed fertility management method.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192 to Engel et al. in view of the Ziegler et al, Hall et al, Dhegenghi, Rabasseda et al and Kent references as applied above. The instant claims differ from those in the patented case because the patented case only recites providing an LHRH-antagonist with stimulation of ovarian follicle growth, ovulation induction and intrauterine insemination, whereas the instant case further recites a programming step involving the LHRH antagonist or a progestogen composition. However, the combination of such a programming method with an infertility treatment is obvious over the teachings of Ziegler et al, Hall et al, Dhegenghi, Rabasseda et al and Kent, as discussed for claims 1 and 4-24 in the 103(a) rejection made above. Accordingly, the instant claims are not patentably distinct from those in the patented case.

Response to Arguments

Applicant's arguments with respect to claims 1 and 4-24 have been considered but are moot in view of the new ground(s) of rejection.

In particular, Applicant's argue that the previously applied references did not provide support for the programming or timing of the assisted reproductive method as provided by step (a) of claim 1. However, as discussed above, this step is obvious in

view of the teachings of Ziegler et al, Garfield et al. and Hall et al, as newly applied above.

The declaration filed by Applicants on December 13, 2005 and signed by Hilde Riethmuller-Winzen has also been fully considered. The declaration argues that the references as applied do not teach programming of the menstrual cycle for assisted reproductive methods. However, as noted above, the references as newly cited make up for this deficiency. The declaration also argues that Garfield et al. teaches administration of contraceptives for the inhibition of ovulation. The Examiner notes that Garfield et al. also teaches that the contraceptives inhibit follicular growth, and Ziegler et al. teaches that contraceptives are used to time or program the onset of the assisted reproductive technique. The declaration further argues that the method has the added benefit of improving the homogeneity of antral follicles during the early follicular phase. However, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The article entitled "Gonadotropin Suppression with Oral Contraceptives before In Vitro Fertilization" by Gonen et al, 1990, teaches providing oral contraceptives before follicle stimulation in vitro fertilization stimulation protocols (see abstract, in particular.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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AMC

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